



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20590
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 937,474	01 21 2003	Sergey Vladimirovich Bryukov	RDID01051US	9514

7590 03 25 2003

Kenneth J Waite
Roche Diagnostics Corporation
9115 Hague Road Building D
PO Box 50457
Indianapolis, IN 46250-0457

EXAMINER

MAYES, LAURIE A

ARTICLE	PAPER NUMBER
---------	--------------

1653

DATE MAILED 03 25 2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,474

Applicant(s)

BIRYUKOV ET AL.

Examiner

Laurie Mayes

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2+5
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claim 1 recites the limitation "the additional mixture" in line 9. There is insufficient antecedent basis for this limitation in the claim. It is suggested that this language be replaced by "an additional mixture".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Mozayeni (US 5,434,079; paper #5). Mozayeni teaches a method for obtaining polypeptides in a cell-free system (col. 1, lines 5-7 and col. 3, lines 5+) by which the reaction mixture is prepared with the use of a reticulocyte lysate (col. 11, lines 1-5; see also col. 7, lines 49+)(present claim 9). The parameters of the cell-free system are chosen (col. 2, lines 10-12), the type and parameters of at least one porous barrier are determined (col. 4, lines 9-14), the reaction mixture and the feeding solution are placed in the reaction module (col. 8, lines 7-9), wherein the components of the feed solution and other parameters, namely, upper and lower limits, such as temperature, concentration, and flow rate may be changed during the synthesis for optimal results and wherein up to four different types of solutions may be added to the mixture resulting in an additional mixture being formed (col. 7, lines 2-35)(present claim 1), wherein at least one

Art Unit: 1653

of the selected components is Mg^{2+} (col. 7, line 66) (present claim 2), wherein the mode of synthesis is translation (see abstract) (present claim 4), the mixture contains ATP and GTP (col. 7, line 66) (present claim 5) which is supplied to the reaction mixture before or during synthesis (col. 7, lines 10-23 and 65-68) (present claim 6, 7), wherein low molecular weight components of the feeding solution are selected by using membranes having different cutoffs for molecular weight (col. 4, lines 52-57) in a continuous flow mode (see abstract and col. 4, lines 14-17) (present claim 8). All of the elements of claims 1, 2 and 4-9 are taught by Mozayeni. Thus claims 1, 2 and 4-9 are anticipated under 35 U.S.C. 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mozayeni in view of Wimmer et al. (US 5,674,729; paper #5). Wimmer et al. teach a process for the synthesis of viral proteins (Fig. 2) in a cell-free medium using NTP (see abstract) and Mg^{++} (col. 10, lines 57-59; Table 1). Wimmer et al. do not teach a method of obtaining polypeptides wherein the upper and lower limits of concentration range for an additional mixture containing these selected components.

Mozayeni teaches a method for obtaining polypeptides in a cell-free system (col. 1, lines 5-7) by which the reaction mixture is prepared with the use of a reticulocyte lysate (col. 11, lines 1-5) (present claim 9), the parameters of the cell-free system are chosen (col. 2, lines 10-12), the

Art Unit: 1653

type and parameters of at least one porous barrier are determined (col. 4, lines 9-14), the reaction mixture and the feeding solution are placed in the reaction module (col. 8, lines 7-9), wherein the components of the feed solution and other parameters, namely, upper and lower limits, such as temperature, concentration, and flow rate may be changed during the synthesis for optimal results and wherein up to four different types of solutions may be added to the mixture resulting in an additional mixture being formed (col. 7, lines 2-35)(present claim 1), wherein at least one of the selected components is Mg^{2+} (col. 7, line 66)(present claim 2). Mozayeni does not teach a method wherein both Mg^{++} and NTP are used for the production of the proteins.

Given the success taught by Wimmer et al. of using Mg^{++} and NTP in the production of viral proteins, it would have been obvious to one of ordinary skill in the art at the time of the invention to use Mg^{++} and NTP in the method of making polypeptides as described by Mozayeni. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 9AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 305-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Art Unit: 1653

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

L. Mayes

Laurie Mayes
Patent Examiner
Art Unit 1653
March 21, 2003

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600